



### Package leaflet: Information for the user

#### Epiduo 0.1% / 2.5% gel Adapalene/Benzoyl Peroxide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet:

1. What Epiduo is and what it is used for
2. What you need to know before you use Epiduo
3. How to use Epiduo
4. Possible side effects
5. How to store Epiduo
6. Contents of the pack and other information

### 1. What Epiduo is and what it is used for

Epiduo is used for the treatment of acne.

This gel combines two active ingredients, Adapalene and Benzoyl peroxide which work together but in different ways:

Adapalene belongs to a group of products known as retinoids and acts specifically on the skin processes that cause acne.

The other active ingredient, benzoyl peroxide, works as an antimicrobial agent and by softening and peeling the outer layer of the skin.

### 2. What you need to know before you use Epiduo

#### Do not use Epiduo:

- If you are pregnant
- If you are planning a pregnancy
- If you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6).

#### Warnings and precautions

- You should not use Epiduo on areas where you have cuts, scrapes, sunburn or eczema.
  - Make sure Epiduo does not get into your eyes, mouth or nostrils, and other very sensitive areas of the body. Should this occur wash these areas immediately with plenty of warm water.
  - Avoid excessive exposure to sunlight and UV lamps.
  - Avoid getting Epiduo on your hair or coloured fabrics as it may bleach them and wash your hands thoroughly after you have used the medicine.
- Talk to your doctor or pharmacist before using Epiduo.

#### Other medicines and Epiduo

- Do not use other acne products (containing benzoyl peroxide and / or retinoids) at the same time as Epiduo.
- Avoid using Epiduo at the same time as cosmetics that are irritant, drying or exfoliate the skin.

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

#### Pregnancy and breast-feeding

DO NOT use Epiduo if you are pregnant or thinking of becoming pregnant. Your doctor can give you more information.

If you fall pregnant while taking Epiduo, the treatment must be discontinued and you should inform your doctor as soon as possible for a further follow-up.

Epiduo can be used during breast-feeding. To avoid contact exposure of the infant, application of Epiduo to the chest should be avoided.

Ask your doctor or pharmacist for advice before taking any medicine.

#### Driving and using machines

Not relevant.

**Epiduo contains propylene glycol (E1520), an ingredient that may cause skin irritation.**

### 3. How to use Epiduo

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Epiduo is only intended for use in adults, adolescents and children aged 9 years and over. This medicine is for external use only.

Apply a thin film of gel evenly over acne affected areas once a day at bedtime, avoiding the eyes, lips and nostrils. The skin should be clean and dry before application. You should wash your hands thoroughly after you have used Epiduo.

Your doctor will tell you how long you will need to use Epiduo.

If you feel that the effect of Epiduo is too strong or too weak, talk to your doctor or pharmacist.

If you experience persistent irritation when applying Epiduo, contact your doctor.

You may be asked to apply a moisturizer, to use the gel less often or to stop for a short time, or to stop using the gel altogether.

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	DIELINES

#### If you use more Epiduo than you should

If you use more Epiduo than you should on your skin, you will not get rid of your acne quicker, but your skin may become irritated and red.

Please contact your doctor or the hospital:

- If you have used more Epiduo than you should.
- If a child has accidentally taken this medicine.
- If you accidentally swallow this medicine.

Your doctor will advise you on action to be taken.

#### If you forget to use Epiduo

Do not apply a double dose to make up for forgotten individual doses.

### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using the product and seek immediate medical attention if you develop throat tightness or swelling of the eyes, face, lips or tongue, feel faint, or have difficulty breathing. Stop using the product if you develop hives or itching of the face or body. The frequency with which these side effects occur is not known.

**Common side effects** (may affect up to 1 in 10 people)

- dry skin
- local skin rash (irritative contact dermatitis)
- burning sensation
- irritation of the skin
- redness
- scaling

**Uncommon side effects** (may affect up to 1 in 100 people)

- itching of the skin (pruritus)
- sunburn

**Not known** (frequency cannot be estimated from the available data): swelling face, allergic contact reactions, swelling of the eyelid, tightness in the throat, pain of skin (stinging pain), blisters (vesicles), difficulty in breathing, skin discolouration (change in skin colour), application site burn.

If skin irritation appears after application of Epiduo, it is generally mild to moderate, with local signs as redness, dryness, scaling, burning and pain of skin (stinging pain), which peak during the first week and resolve without additional treatment.

Application site burns, mostly superficial but more severe cases involving blistering have been reported.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

##### United Kingdom

Yellow Card Scheme

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

##### Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store Epiduo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Discard the tube or pump 6 months after first opening.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. Contents of the pack and other information

#### What Epiduo contains

- The active substances are: Adapalene and benzoyl peroxide. 1 g of gel contains 1 mg (0.1 %) adapalene and 25 mg (2.5 %) benzoyl peroxide.
- The other ingredients are: docusate sodium, disodium edetate, glycerol, poloxamer, propylene glycol (E1520), Simulgel 600 PHA (copolymer of acrylamide and sodium acryloyldimethyltaurate, isohexadecane, polysorbate 80, sorbitan oleate) and purified water.

#### What Epiduo looks like and contents of the pack

Epiduo is a white to very pale yellow opaque gel.

Epiduo is available in:

White plastic tubes with screw-cap containing 5g, 15g, 30g, 45g, 60g or 90g (not all pack sizes may be marketed).

White pumps with snap on cap containing 15 g, 30 g, 45 g or 60 g (not all pack sizes may be marketed).

#### Marketing Authorisation Holder and Manufacturer

##### Marketing Authorisation Holder

UK MAH: Galderma (UK) Limited, Meridien House, 69-71 Clarendon Road, Watford, Herts., WD17 1DS, UK.

IE MAH: Galderma International S.A.S., Tour Europlaza, La Défense 4, 20 Avenue André Prothin, France.

##### Manufacturer

Laboratoires Galderma

ZI – Montdésir - 74540 Alby sur Chéran - France

PL 10590/0057

PA 22743/007/001

**This medicinal product is authorised in the Member States of the EEA under the following names :**

Denmark: Epiduo

Croatia, Czech Republic, Portugal, Slovakia, Spain: Epiduo 1 mg/g + 25 mg/g gel

Hungary, Netherlands: Effezel 1 mg/g + 25 mg/g gel

Bulgaria, Estonia, Latvia, Lithuania, Romania: Epiduo 1 mg/25 mg/g gel

Slovenia: Epiduo 1 mg/25 mg v 1 g gel

Other countries: Epiduo 0.1% / 2.5% gel

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